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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,730	02/19/2002	Yun Hwang Choe	213.1077 CRNL-U	5356

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/078,730	Applicant(s) CHOE ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendment and remarks dated 10-24-05 is acknowledged.

Claims 1-22 are pending in the instant application.

In response to the amendment, the following is a new rejection applied to the claim 4:

Claim Rejections - 35 USC § 112

1. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Instant claim recites the new limitation "provided that at least one of D'1, D"2, D"1 and D2 is not OH", which is not supported by the specification. Applicants state that page 6 and page 10 provide support for the claimed limitation. However, a careful review of the specification does not reveal any support for the newly added limitation. Accordingly, the claim limitation is a new matter.

2. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim recites the new limitation "provided that at least one of D'1, D"2, D"1 and D2 is not OH" is vague and indefinite because the limitation recites the variable D"2

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twice and it is not clear if applicants intend to claim D'2 and D"2. If so, appropriate correction is requested.

The following rejection of record has been maintained:

Claim Rejections - 35 USC § 103

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/53951 (WO).

WO '951 teaches terminally branched polymeric linkers and polymeric conjugates containing the linkers for forming long-acting conjugates of bioactive materials. In particular, WO teaches compounds of formula I (page 3), where the variables J, E, Y, M, Z etc., (described on pages 3-5). Furthermore, the compounds listed on pages 9-10 meet the claimed compound, particularly, the compound of claim 3. WO further teaches that R1 is a polymeric residue, which includes polyalkylene oxides such as polyethylene glycols (page 12); and also teaches the molecular weight of polymers in the range 2,000 to 100,000 (page 13, lines 15-25). WO also teaches the linking a number of drugs such as podophyllotoxin, gemcitabine, ciclopirox etc to be delivered with the prodrug compounds (page 16-17). The conjugated prodrugs of WO are described on pages 24, which read on the instant claimed prodrugs (claim 18). WO differs from the instant claims in the presence of [R2-C-R3]_m, which is not present in the claimed compound. However, WO teaches q=zero or positive integer (page 4, line 19). Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use q as 0 or positive integer and still achieve a prodrug having same efficiency in delivering the desired drug.

Response to Arguments

Applicant's arguments filed 10-24-05 have been fully considered but they are not persuasive.

Applicants argue that while previously presented claims require that D1 and D2 both cannot be OH, the present claims (amended) clarify that at least one of D'1, D"2, D"1 and D2 is not OH, which require the terminal groups to include at least one of moiety IV and V that facilitate the benzyl-elimination reaction to regenerate or release the drug or biologically active moiety attached thereto. It is argued that there is no disclosure in the cited reference to provide the specific moieties of IV and V, as required by the newly added limitation. Applicants arguments are not persuasive because the present amendment is only limited to claim 4 and not to all the claims. With respect to claim 4, please refer to the new matter rejection. Because claims 1-3 and 5-22 are not limited by the newly added claims, the argument that the claims are unobviousness over the prior art teachings is not persuasive. Accordingly, the rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the


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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lakshmi S Channavajjala
Examiner
Art Unit 1615


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

January 6, 2006